

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**Washington, D.C. 20460**



**OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION**  
**Antimicrobial Division**

**4/6/2016**

**DP BARCODE:** 431698

**MRIDs:** 463600-01, 472393-01, 497567-01, 497567-02, 497567-03, 497567-04, and 497567-05

**SUBJECT:** Sterilex Ultra Disinfectant Cleaner Solution 1

**REG. NO. OR FILE SYMBOL:** 63761-8

**DOCUMENT TYPE:** Product Chemistry Review

**Manufacturing-use product** ☐ **OR** **End-use product**☒

**INGREDIENTS (PC Codes):** 000595, 069104, and 069154

**CAS Number:** 7782-84-1, 53516-76-0, and 85409-23-0

**TEST LAB:**

**SUBMITTER:** Sterilex Corp.

**GUIDELINE:**

**COMMODITIES:**

**REVIEWER:** Sergey Alekseyev

**ORGANIZATION:** AD/PSB/CTT

**APPROVER:** Karen P. Hicks

**APPROVED DATE:**

**COMMENT:**

**From:** Sergey Alekseyev, Chemist  
Product Science Branch, CT Team  
Antimicrobials Division (7510P)



**Thru:** Karen P. Hicks, CT Team Leader  
Product Science Branch  
Antimicrobials Division (7510P)



**To:** Julie Chao/Timothy Young  
PM Team 33

**APPLICANT:** Sterilex Corp.

**Action code:** (A540) New Product; Non-Fast Track; FIFRA Sec. 2(MM) Uses

**Formulation from Label**

Active Ingredient Names	%wt (label)
Hydrogen peroxide	6.30
BTC 776 (Alkyl* dimethyl benzyl ammonium chloride *(60% C14, 30% C16, 5% C18, 5% C12))	3.00
BX-673 (Alkyl* dimethyl ethylbenzyl ammonium chloride *(68% C12, 32% C14))	3.00

**BACKGROUND:**

Sterilex Corp. provided EPA Form 8570-4 (Confidential Statement of Formula), one basic and five alternate formulations, dated 10/22/2015; MRID Nos. 463600-01, 472393-01, 497567-01, 497567-02, 497567-03, 497567-04, and 497567-05; a label, dated 09/10/2014; and EPA Form 8570-35 (Data Matrix), dated 10/28/2015. The registrant is requesting product chemistry review of the subject product.

**FINDINGS:**

1. EPA Reg. No. **63761-8** is an end-use product containing the active ingredient Hydrogen peroxide, BTC 776 (Alkyl\* dimethyl benzyl ammonium chloride \*(60% C14, 30% C16, 5% C18, 5% C12)), and BX-673 (Alkyl\* dimethyl ethylbenzyl ammonium chloride \*(68% C12, 32% C14)), with a label claim nominal concentration of 6.3%, 3.0%, and 3.0%, respectively; and other ingredients content of 87.7%. The product is for sanitizing and disinfection of surfaces and killing of germs. The product is produced by a non-integrated system.
2. The CSFs for all formulations are acceptable. The nominal concentration of the active ingredient agrees with that on the label, meeting PR Notice 91-2. The certified limits for all ingredients are acceptable in accordance with 40 CFR §158.350. All ingredients are cleared for use in pesticide formulations.
3. Data reported in MRID No. 463600-01, 472393-01, 497567-01, 497567-02, 497567-03, 497567-04, and 497567-05 satisfy the product chemistry data requirements under Subgroups A and B, which pertain to Product Identity and Composition, and Physical and Chemical Properties, respectively.
4. The Ingredients Statement on the draft label is acceptable as per 40 CFR §156.10(g) and PR Notices 91-2, 97-5, and 97-6. The Storage and Disposal Statements are acceptable in accordance with 40 CFR §156.10(i)(2)(ix) and PR Notice 83-3.

**CONCLUSIONS:**

The registrant has satisfied the product chemistry requirements for the reregistration of EPA Reg. No. **63761-8**.

## **Product Chemistry Data**

### **Subgroup A: Series 830.1550 - 830.1800 (40 CFR 158.155 - 158.180)**

<b>GUIDELINE REFERENCE NO. (GRN)/ TITLE 830</b>	<b>40 CFR §</b>	<b>MRID Number</b>	<b>Data Fulfilled</b>
.1550 Product Identity and Composition	158.320	CSF	Y
.1600 Description of Materials Used to Produce the Product	158.325	497567-02	Y
.1620 Description of Production Process	158.330		N/A
.1650 Discussion of Formulation Process	158.165	497567-02	Y
.1670 Discussion of Formation of Impurities	158.167	497567-02	Y
.1700 Preliminary Analysis	158.345		N/A
.1750 Certified Limits	158.350	497567-02	Y
.1800 Enforcement Analytical Method	158.355	497567-02	Y



**Subgroup B: Series 830.6302 - 7950 (40 CFR 158.190)**

<b>Guideline Reference No. (GRN) / Title 830</b>	<b>Value or Qualitative Description</b>	<b>MRID Number</b>	<b>Data Fulfilled</b>
.6302 Color	Clear, colorless	463600-01	Y
.6303 Physical State	Liquid	497567-04	Y
.6304 Odor	None	463600-01	Y
.6313 Stability to Normal and Elevated Temperature, Metals, and Metal Ions	Not applicable. The product is not TGAI/MP.		N/A
.6314 Oxidation/Reduction Chemical Incompatibility	The product contains reducer (reacts with KMnO <sub>4</sub> ).	497567-02	Y
.6315 Flammability/ Flame Extension	The product does not contain flammable liquid.	CSF	N/A
.6316 Explodability	The product is not potentially explosive.	497567-03	N/A
.6317 Storage Stability	The product is stable after 1 year at RT.	472393-01	Y
.6319 Miscibility	The product is not to be mixed with petroleum distillate.	Label	N/A
.6320 Corrosion Characteristics	No signs of corrosion attack upon the package (HDPE) after 1 year at RT.	472393-01	Y
.6321 Dielectric Breakdown Voltage	The product is not intended to be used around electrical equipment.	Label	N/A
.7000 pH	5.65	463600-01	Y
.7050 UV/Visible Light Absorption	Not applicable. The product is not TGAI/MP.		N/A
.7100 Viscosity	1.783 cSt at 23.0 °C; 1.048 cSt at 44.5 °C	497567-04	Y
.7200 Melting Point	Not applicable. The product is not TGAI/MP.		N/A
.7220 Boiling Point	Not applicable. The product is not TGAI/MP.		N/A
.7300 Density/Bulk Density	1.0198	463600-01	Y
.7370 Dissociation Constant in Water	Not applicable. The product is not TGAI/MP.		N/A
.7550 Octanol/Water Partition Coefficient	Not applicable. The product is not TGAI/MP.		N/A
.7840 Solubility to Water and Organic Solvents	Not applicable. The product is not TGAI/MP.		N/A
.7950 Vapor Pressure	Not applicable. The product is not TGAI/MP.		N/A

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable; G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived

